

CPR PART 12

LICENSES FOR MEDICAL USE OF RADIOACTIVE SOURCES IN TELETHERAPY

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LICENSES FOR MEDICAL USE OF RADIOACTIVE SOURCES IN TELETHERAPY

CPR PART 12

I. GENERAL PROVISIONS

Section 1. Purpose and Scope.

- (a) This Part prescribes the requirements for issuance of licenses for the medical use of radioactive sources in Teletherapy unit and Gamma Stereotactic Radiosurgery (GSR) unit;
- (b) This Part also provides requirements for the safety and security of radioactive sources in Teletherapy and GSR unit.
- (c) The requirements and provisions in this Part provide for the protection of health and safety of the public, patients, and workers and are in addition to other requirements in the **Code of PNRI Regulations (CPR or Code)**.
- (d) The provisions and requirements of this Part shall be applied in conjunction with the radiation safety requirements of CPR Part 3, radioactive source security requirements of CPR Part 26, and the safe transport requirements of CPR Part 4.
- (e) This Part does not relieve the licensee from complying with the applicable requirements of other responsible agencies of government.

Section 2. Definitions.

As used in this Part:

- (a) **“Accident”** means any unintended event, including operating errors, equipment failures or other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection or safety;
- (b) **“Act”** means Republic Act No. 2067, otherwise known as the Science Act of 1958, as amended, and Republic Act 5207, otherwise known as the Atomic Energy Regulatory and Liability Act of 1968, as amended;
- (c) **“ALARA”** (as low as reasonably achievable) means making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practicable:
 - (1) Consistent with the purpose for which the licensed activity is undertaken; and
 - (2) Taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety and other societal and socio - economic considerations;

- (d) **“Assistant Radiation Safety Officer”** means the individual who is identified in the license issued pursuant to this Part to perform the duties and responsibilities of the RSO in his/her absence;
- (e) **“Authorized User”** means a physician who is identified as an authorized user in a license issued by PNRI that authorizes the medical use of sealed radioactive sources in teletherapy and GSR units;
- (f) **“Decommissioning”** means removing a facility or site safely from service and reducing residual radioactivity that permits:
 - (1) Release of the facility or site for unrestricted use and termination of the license; or
 - (2) Release of the facility or site under restricted conditions and termination of the license;
- (g) **“Dedicated check source”** means a radioactive source that is used to assure the proper operation of a radiation detection or measurement device;
- (h) **“Disused source”** means a radioactive source no longer in use or intended to be used for the purpose which the license has been granted;
- (i) **“Full Calibration”** means the measurements that include determination of: output for the reference field size or the range of field sizes and for the distance or range of distance used for medical use; coincidence of the radiation field; uniformity of the radiation field; timer accuracy and linearity over the range of use; on-off error; and accuracy of all distance measuring and localization devices in medical use;
- (j) **“Gamma stereotactic radiosurgery”** means a method of delivering low-intensity gamma rays to the target abnormality for the purpose of treating brain tumors, arteriovenous malformations and brain dysfunctions;
- (k) **“Investigation Level”** means the value of a quantity such as effective dose, intake, or contamination per unit area or volume at or above which an investigation must be conducted;
- (l) **“Licensee”** means a holder of a valid license issued by PNRI for medical use of radioactive sources in a teletherapy and GSR unit;
- (m) **“Medical Exposure”** means an exposure incurred by patients as part of their own medical treatment;
- (n) **“Medical Physicist”** means the individual identified as the medical physicist in a PNRI license issued pursuant to this Part;
- (o) **“Medical use”** means the intentional external administration of radiation from radioactive source to human beings in the practice of medicine;
- (p) **“Output”** means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of conditions;
- (q) **“Person”** means:
 - (1) any individual, firm, partnership, association, trust, estate, private or public body, whether corporate or not, or any government agency other than the Institute, any province, city, municipality, or any political subdivision of the Republic of the Philippines or any political entity within the Philippines; and
 - (2) any legal successor, representative, agent, or agency of the foregoing;

- (r) **“Physician”** means a medical doctor licensed or authorized by the Professional Regulatory Commission to prescribe drugs in the practice of medicine in the Philippines;
- (s) **“PNRI”** means the Philippine Nuclear Research Institute and its duly authorized representative;
- (t) **“Radiation Safety Officer”** means the individual designated in the license issued pursuant to this Part to be responsible for implementing the radiation safety program of the licensee;
- (u) **“Radioactive Material”** means any material containing radionuclide where both the activity concentration and the total activity exceed the values specified in Appendix A of CPR Part 3;
- (v) **“Radioactive Source”** means any radioactive material that is permanently sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It also means any radioactive material released if the radioactive source is leaking or broken but does not mean source encapsulated for disposal, or nuclear material within the nuclear fuel cycles of research or power reactor;
- (w) **“Radiotherapy Technologist”** means an individual authorized in the license issued pursuant to this Part to be responsible in operating the teletherapy or GSR unit;
- (x) **“Radioactive source and device registry”** means the certificate issued by the competent authority in the country of origin of the radioactive source that contains all the registration certificates that summarize the radiation safety information for the radioactive source and device and describes the licensing and use conditions approved for the product, otherwise known as “Sealed source and device registry”;
- (y) **“Secondary Standard Dosimetry Laboratory”** means a national laboratory recognized by the PNRI for the calibration of equipment/instrument or devices within the country and is traceable to a primary standard laboratory;
- (z) **“Security”** means measures to prevent unauthorized access or damage to, and loss, theft, or unauthorized transfer of radioactive sources;
- (aa) **“Service provider”** means an organization authorized by PNRI to provide technical services;
- (bb) **“Teletherapy”** means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject;
- (cc) **“Worker”** means any individual who works, whether full time, part time or temporarily, for a licensee and who has recognized rights and duties in the license in relation to occupational radiation protection;

Section 3. Interpretation.

Except as specifically authorized by PNRI in writing, no interpretation of the meaning of the regulations by any officer or employee of PNRI other than a written interpretation by the Director will be recognized to be binding upon the PNRI.

Section 4. *Communication.*

All communication and reports concerning the license and the regulations in this Part shall be addressed to the Director, Philippine Nuclear Research Institute, Commonwealth Avenue, Diliman, Quezon City, Metro Manila.

Section 5. *Activities Requiring License.*

No person shall acquire, receive, possess, own, use, transfer or import radioactive sources for medical use in a teletherapy unit or gamma stereotactic radiosurgery (GSR) unit except in accordance with a license issued by PNRI pursuant to this Part.

Section 6. *Application for New License and Renewal of License.*

- (a) An application for a new or renewal of license pursuant to this Part shall be filed on PNRI/NRLSD Form -012, "Application for a License for the Medical Use of Radioactive Sources in Teletherapy", in duplicate copies.
- (b) Each application for a license pursuant to this Part must be duly affirmed and notarized and shall be signed by the applicant or a person duly authorized to act for and on his behalf upon submission to PNRI.
- (c) The applicant must show proof of authenticity of business name issued by the Securities and Exchange Commission and the current business permit or specific authorization issued by the responsible government agency.
- (d) The application shall adequately describe the necessary information required in the application form in accordance with the technical, safety, and security requirements specified in this Part and will be accepted and processed only when PNRI has determined the completeness of the submitted information, and payment of corresponding fees prescribed in CPR Part 22 has been made.
- (e) PNRI, may, at any time after the filing of the application, require further statements to enable PNRI to determine whether the license should be granted or denied.

Section 7. *Issuance of License.*

An application for a license pursuant to this Part shall be approved and license shall be granted if:

- (a) The application is for the purpose authorized by the Act;
- (b) The locations and areas where the radioactive source will be used and stored are in accordance with the safety and security requirements of the Code;
- (c) The applicant's proposed equipment and facilities are adequate to protect health and safety of workers, patients, and the public and minimize danger to life or property as well as to ensure the security of the radioactive sources;
- (d) The proposed authorized user, medical physicist, and radiotherapy technologist meet the requirements in Sec. 44, 45, and 47 of this Part;
- (e) The applicant has designated a Radiation Safety Officer (RSO) and Assistant Radiation Safety Officer (ARSO), who meet the requirements in Sec. 46 of this Part. The designated

RSO and ARSO shall both consent and agree in writing, and shall ensure the effective implementation of the radiation safety and source security programs in accordance with approved procedures and the regulatory requirements;

- (f) The authorities, duties, and responsibilities of the RSO on matters affecting radiation safety have been established and stated in writing;
- (g) The applicant has submitted technical specifications for the equipment and source in compliance with Section 19 of this Part;
- (h) The applicant has a program for training and re-training of workers;
- (i) The applicant possesses a calibrated and operable radiation survey instrument required in Sec. 31 of this Part;
- (j) The applicant has submitted a radiation safety program that addresses CPR Part 3 and the technical requirements of this Part;
- (k) The applicant has established procedures for the transport of radioactive sources in accordance with the requirements of CPR Part 4 "Regulations for the Safe Transport of Radioactive Material in the Philippines.";
- (l) The applicant's program on the security of the radioactive sources is in accordance with the requirements of CPR Part 26, "Security of Radioactive Sources" for Category 1 Sources;
- (m) The applicant has established and submitted to PNRI an emergency plan in accordance with the requirements of Section 17 of CPR Part 3;
- (n) The applicant has provided PNRI documents from the manufacturer of the equipment on the maintenance and service to the teletherapy or GSR unit;
- (o) The applicant has established decommissioning plan for the facility and disposal plans for radioactive source;
- (p) The applicant has ensured that disused sources shall be returned to the original supplier or manufacturer in the country of origin; and
- (q) The applicant has paid all applicable fees in accordance with CPR Part 22.

Section 8. Terms and Conditions of License.

- (a) Each license issued shall be subject to the applicable provisions of the Act, specific conditions of the license and to all relevant rules, regulations, and orders of PNRI.
- (b) The license shall be valid for a period as may be determined by PNRI.
- (c) PNRI may incorporate in any license issued pursuant to this Part at the time of issuance or thereafter by appropriate notification, rule or order, such additional requirements and conditions with respect to the license as it deems appropriate or necessary in order to protect health and safety, as well as ensure the security of the radioactive source;
- (d) Neither the license issued nor right granted under the license shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person, unless PNRI, after securing full information:

- (1) finds that the proposed transfer, assignment or disposition is in accordance with the regulations of the Code and provisions of the Act; and
 - (2) consents in writing to the proposed transfer, assignment or disposal.
- (e) Upon the approval of PNRI of a proposed transfer, pursuant to (d) of this Section, the transferor shall ensure that the transferee is provided with all the information required by PNRI.
- (f) Each licensee shall confine his possession and use of the radioactive source described in the license to the location and purpose authorized in the license.
- (g) Each licensee shall strictly follow the regulatory requirements regarding the renewal, amendment and expiration of the license.
- (h) Each licensee shall maintain and retain records as required in this Part;
- (i) Each licensee shall keep a copy of the existing license and applicable regulations of the Code and make them available at authorized locations indicated in the license.

Section 9. Amendment of License.

- (a) An application for amendment of a license shall be filed in PNRI/NRLSD Form-012A, "Application for Amendment of License", and shall specify in what respect the licensee desires his license to be amended and the grounds for such amendment. The corresponding license amendment fee required in CPR Part 22 shall be paid upon filing of the application.
- (b) A licensee shall apply for and must receive a license amendment before:
- (1) it receives and uses radioactive sources other than what is indicated in the license;
 - (2) it permits anyone to work as an authorized user, medical physicist, RSO or radiotherapy technologist other than those previously authorized in the license;
 - (3) it orders and receives radioactive source in excess of the activity authorized in the license;
 - (4) any major change in teletherapy unit or gamma stereotactic unit ;
 - (5) making any change in the treatment room shielding or structural modification in the licensed facility;
 - (6) transferring the location of the teletherapy unit or gamma stereotactic unit within the medical facility;
 - (7) it implements any major change in the approved radiation safety program; or
 - (8) any substantial change in any conditions of the license takes effect.

Section 10. Expiration of License.

- (a) Each license shall expire at the end of the day of the expiration date stated in the license. Pending any PNRI discretion on the disposition of the license, the licensee shall keep radioactive sources under safe and secure storage in accordance with the security plan.
- (b) If the license is deemed to have expired and will not be renewed, the licensee shall notify PNRI accordingly and shall cease to engage in any licensed activity involving the radioactive

sources except to keep the radioactive sources under safe and secure storage until determined by PNRI.

- (c) The discontinued use of radioactive sources as a result of the expiration of the license shall not relieve the licensee of the responsibility to cause the decommissioning of the facility and termination of the license.

Section 11. *Renewal of License.*

- (a) If the licensee decides to renew the license, the licensee must formally notify PNRI at least thirty (30) days before the expiration date of license, by submitting an application for renewal of the license in accordance with Section 6 of this Part. If an application for license renewal is filed in the proper form, the existing license shall be deemed to remain valid until PNRI has taken final action on whether to renew or deny the license, but in no case shall it be more than thirty (30) days after the expiration of the existing license. The corresponding license renewal fee must be paid upon filing of the application for license renewal.
- (b) An application for license renewal that is filed less than thirty (30) days before the expiration date of the license shall be assessed a surcharge equivalent to twenty-five (25) percent of the prescribed license renewal fee. The existing license shall be deemed to remain valid until PNRI has taken final action on whether to renew or deny the license, but in no case shall it be more than thirty (30) days after the expiration date of the existing license. This does not however preclude the imposition of any regulatory action arising from the late filing of the application. The corresponding license renewal fee must be paid upon filing of the application for license renewal.

Section 12. *Specific Condition for Expired License.*

If an application for license renewal is filed after the expiration date stated in the license but not more than thirty (30) days after that date, the licensee shall immediately cease from performing any licensed activity except to keep all radioactive sources under safe and secure storage in accordance with the security plan until PNRI has determined to renew or deny the license. This does not however preclude the imposition of any regulatory action arising from the late filing of the application. The licensee shall be assessed a surcharge equivalent to fifty (50) percent of the applicable fees if the application for license is accepted by PNRI.

Section 13. *Termination of License.*

- (a) The termination of a license may be initiated at any time at the request of the licensee.
- (b) Before the license can be terminated, the licensee must:
 - (1) discontinue all activities involving licensed radioactive sources;
 - (2) transfer or dispose of all licensed materials which were in his possession in accordance with the regulations;
 - (3) determine by a survey or other means that no contamination levels in excess of the limits for controlled areas exist in his facilities; and
 - (4) assure that the required records are complete and up-to-date.
- (c) To be relieved of the responsibilities for the material and other conditions in his license, the licensee shall submit to PNRI:
 - (1) his request that the license be terminated;

- (2) a certified statement that he no longer has in his possession any radioactive source requiring a license; and
 - (3) a listing of the radioactive source transferred or disposed of and the person to whom the material was transferred or the method of disposal for each item;
 - (4) the statement of a qualified expert that his facilities are not contaminated;
 - (5) an agreement that his records and facilities will be available for inspection by PNRI at a mutually agreeable date within the next three months.
- (d) When these procedures have been satisfactorily completed, PNRI will inform the licensee and formally terminates the license.

II. EXEMPTIONS AND ADDITIONAL REQUIREMENTS

Section 14. Specific Exemptions.

The PNRI may, upon application by the licensee or upon its own initiative, grant such exemptions from the regulations in this Part as it determines are authorized by law and will not result in undue hazard to life, property and the environment.

Section 15. Additional Regulatory Requirements.

The PNRI may, by rule, regulation, or order impose upon any licensee such requirements, in addition to those established in this Part, as it deems appropriate or necessary to protect the health and safety of the public or to minimize danger to life, property and the environment.

III. ADMINISTRATIVE REQUIREMENTS

Section 16. Radiation Safety Program.

- (a) Each licensee shall develop and implement a written radiation protection program that includes provisions of Chapter II of CPR Part 3.
- (b) Each licensee shall develop and implement an ALARA program that must include the following:
 - (1) Management formal commitment to the ALARA philosophy;
 - (2) Periodic review of the radiation safety program and provision of continuing education and training for all personnel who work with or in the vicinity of the teletherapy facility;
 - (3) Notice to workers of the program's existence and workers' duties and responsibilities to help keep doses ALARA;
 - (4) Establishment of Investigation Levels (IL) and description of actions to be taken if radiation exposure exceeds the IL; and
 - (5) Review of the doses received by workers.

Section 17. Radiation Safety Officer (RSO) and Assistant Radiation Safety Officer (ARSO).

- (a) The licensee shall designate RSO and ARSO, to be responsible for implementing the radiation safety program. The licensee, through the RSO, shall ensure that radiation safety activities are being performed in accordance with licensee's approved procedures and regulatory requirements. The ARSO shall act for and in behalf of RSO in his absence.

- (b) The licensee shall establish and state in writing the authority, duties, and responsibilities of the Radiation Safety Officer.
- (c) The licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources and management prerogative to:
 - (1) identify radiation safety problems,
 - (2) initiate, recommend, or provide corrective actions,
 - (3) stop unsafe practices,
 - (4) verify implementation of corrective actions.
 - (5) coordinate the establishment, maintenance, drills/exercise of emergency plans and procedures.

Section 18. Radiation Safety Committee (RSC).

Each medical institution shall establish a RSC to oversee the medical use of radioactive sources including uses for nuclear medicine, teletherapy and brachytherapy, if applicable.

- (a) The Committee must meet the following administrative requirements:
 - (1) Membership must consist of at least **five** (5) individuals and must include an authorized user and the RSO of each type of use permitted in the license, a representative of the nursing service, and a representative of management who is neither an authorized user nor a RSO. Other members may be included as the licensee deems appropriate;
 - (2) The committee must establish a program for the conduct of meetings, maintenance of records and submission of reports to PNRI;
 - (3) The committee must meet at least quarterly and minutes of the meetings shall be kept for inspection by the PNRI.
- (b) To oversee the use of licensed material, the Committee must:
 - (1) Review recommendations on ways to maintain individual and collective doses ALARA;
 - (2) Review, the training and experience requirements in Sections 44, 45, 46 and 47 of this Part, and approve or disapprove any individual who is to be listed as an authorized user, the RSO, a Medical Physicist or radiotherapy technologist before submitting a license application or request for amendment or renewal;
 - (3) Review **quarterly**, with the assistance of the RSO, a summary of the occupational radiation dose exposure records of all personnel working with radioactive source and records of radiation level surveys;
 - (4) Review **quarterly**, with the assistance of the RSO, all incidents involving radioactive source with respect to cause and subsequent actions taken;
 - (5) Review **annually**, with the assistance of the RSO, the radiation safety program in accordance with the regulations and the conditions of the license; and
 - (6) Provide PNRI a report on their accomplished activities as a prerequisite to the renewal of the license.

IV. TECHNICAL REQUIREMENTS

Section 19. Teletherapy Equipment and Source.

The technical specifications for the teletherapy equipment and sources shall conform with relevant international standards or its equivalent national standards.

Section 20. Classification of Work Areas.

A licensee shall classify work areas into controlled and supervised areas and comply with the requirements in Sec. 13.6 of CPR Part 3.

Section 21. Personnel and Individual Monitoring.

A licensee shall provide workers with personnel monitoring devices such as film badge or TLD and comply with Sec. 13.9 of CPR Part 3.

Section 22. Installation, Maintenance and Repair.

Only persons specifically authorized or licensed by the PNRI in accordance with CPR Part 25 shall:

- (a) Install or remove a teletherapy radioactive source or relocate a teletherapy equipment that contains a radioactive source; or
- (b) Maintain, or repair a teletherapy equipment that involves work on the source shielding, source driving unit or other electronic or mechanical component that could expose the source, reduce the shielding around the source, or compromise the radiation safety of the unit or the source.

Section 23. Safety Procedures and Instructions.

- (a) A licensee shall:
 - (1) Secure the unit, the console, the console keys, and the treatment room when not in use or unattended.
 - (2) Develop, implement, and maintain written procedures for responding to an abnormal situation when the radiotherapy technologist is unable to place the source in the shielded position or remove the patient from the radiation field with controls from outside the treatment room. The procedures must include:
 - (i) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;
 - (ii) The steps for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and
 - (iii) The names and telephone numbers of the authorized users, medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.
- (b) Each licensee shall post instructions at the unit console to inform the radiotherapy technologists of:
 - (1) The location of the procedures required by paragraph (a)(2)) of this Section; and
 - (2) The names and telephone numbers of authorized users, the Medical Physicists, Radiation Safety Officer, and the Assistant Radiation Safety Officer to be contacted if the unit or console operates abnormally.

- (c) A licensee shall provide instructions, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties in:
 - (1) The procedures identified in paragraph (a)(2) of this Section; and
 - (2) The operating procedure for the unit.

Section 24. Safety Precautions.

- (a) A licensee shall control access to the treatment room by a door at each entrance.
- (b) A licensee shall equip each entrance to the treatment room with an electrical interlock system that will:
 - (1) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;
 - (2) Cause the source(s) to be shielded when an entrance door is opened; and
 - (3) Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.
- (c) A licensee shall equip each entrance to the treatment room with a beam condition indicator light.
- (d) A licensee shall require any individual entering the treatment room to assure through the use of appropriate radiation monitors that radiation levels have returned to ambient levels.
- (e) A licensee shall install in each teletherapy treatment room a permanent radiation monitor capable of continuously monitoring beam status;
 - (1) The radiation monitor must:
 - (i) provide visible indication of a teletherapy unit malfunction that results in an exposed or partially exposed source, and must be observable by an individual entering the teletherapy room.
 - (ii) be equipped with a backup power supply separate from the power supply to the teletherapy unit. This backup power supply may be a battery system.
 - (iii) be checked with a check source for proper operation each day before the teletherapy unit is used for treatment of patients.
 - (2) A licensee shall maintain a record of the check required by paragraph (e)(1)(iii) of this section for two years. The record must include the date of the check, notation that the monitor indicates when its detector is and is not exposed, and the name and signature of the individual who performed the check.
 - (3) If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy room to use a survey instrument to monitor for any malfunction of the source mechanism that may result in an exposed or partially exposed source. The survey instrument must be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in paragraph (e)(2) of this Section.
 - (4) A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

- (f) A licensee shall construct or equip in each treatment room a system that will permit continuous observation of the patient from the treatment unit console during irradiation.
- (g) A licensee shall provide for a constant two-way voice communication between the patient and the team outside the treatment room.
- (h) For gamma stereotactic radiosurgery units, a licensee shall require an authorized user and Medical Physicist to be physically present throughout all patient treatments involving the unit.

Section 25. Dosimetry Equipment.

- (a) A licensee shall have a calibrated dosimetry system available for use. The system must have been calibrated by a Secondary Standard Dosimetry Laboratory (SSDL).
- (b) The calibration must have been performed within the previous two (2) years and after any servicing that may have affected system calibration.
- (c) The dosimetry system must be calibrated using internationally acceptable protocol or equivalent national protocol.
- (d) The licensee shall retain a record of each calibration during the useful life of the machine. For each calibration, the record must include the date, the model numbers and serial numbers of the instruments that were calibrated as required by paragraphs (a) of this section, the correction factor that was determined from the calibration, the names and signature of the individuals who performed the calibration.

Section 26: Quality Control of Teletherapy Units.

- (a) A licensee shall perform daily, monthly and annual tests on the teletherapy units in accordance with the national protocol "Manual for the Quality Assurance/Quality Control Test Procedures for Co-60 Teletherapy Machines in the Philippines" developed by the Philippine Organization of Medical Physicists in coordination with the Bureau of Health Devices and Technology and the PNRI.
- (b) A licensee authorized to use a teletherapy unit for medical use shall perform or cause to be performed full calibration measurements on each teletherapy unit other than annually and during the commissioning before medical use following:
 - (1) replacement of the source or following reinstallation of the teletherapy unit in a new location; and
 - (2) any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly.
- (c) The quality control tests for teletherapy units shall be performed by the licensee's Medical Physicist.
- (d) A licensee shall submit initial report of the tests and retain a record of the succeeding tests for the duration of the use of the teletherapy unit source. The record must include the date of the conduct of the tests, the manufacturer's name, model number, and serial numbers of the instruments used, and the results of the tests/measurements and the signature of the Medical Physicist.

Section 27. Full Calibration Measurements on Gamma Stereotactic Radiosurgery Unit.

- (a) A licensee shall perform or cause to be performed full calibration measurements on the GSR unit:
 - (1) Before the first medical use of the unit;
 - (2) Before medical use under the following conditions:
 - (i) Whenever spot-check measurements indicate that the output differs by more than **three percent** (3%) from the output obtained at the last full calibration corrected mathematically for radioactive decay;
 - (ii) Following replacement of the sources or following reinstallation of the GSR unit in a new location; or
 - (iii) Following any repair of the teletherapy unit that includes removal of the sources or major repair of the components associated with the source exposure assembly; and
 - (3) At intervals not exceeding **one (1) year**, with the exception that the relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.
- (b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of:
 - (1) The output within +/-3 percent;
 - (2) Relative helmet factors;
 - (3) Isocenter coincidence;
 - (4) Timer constancy, accuracy and linearity over the range of use;
 - (5) On-off error;
 - (6) Trunnion centricity;
 - (7) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
 - (8) Helmet microswitches;
 - (9) Emergency timing circuits; and
 - (10) Stereotactic frames and localizing devices (trunnions).
- (c) A licensee shall use the dosimetry system to measure the output for one set of exposure conditions.
- (d) A licensee shall correct mathematically the outputs determined in paragraph (b) (1) of this section for physical decay at intervals not exceeding **one (1) month**.
- (e) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (d) of this section must be performed by the Medical Physicist.
- (f) A licensee shall retain a record of each calibration.

Section 28. Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Unit.

- (a) A licensee shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit:
 - (1) Monthly;
 - (2) Before the first use of the unit on a given day; and
 - (3) After each source installation.
- (b) A licensee shall perform the measurements required by paragraph (a) of this section in accordance with written procedures established by the teletherapy physicist.

- (c) To satisfy the requirements of paragraph (a)(1) of this section, spot-checks must, at a minimum:
- (1) Assure proper operation of:
 - (i) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
 - (ii) Helmet microswitches;
 - (iii) Emergency timing circuits; and
 - (iv) Stereotactic frames and localizing devices (trunnions).
 - (2) Determine:
 - (i) The output for one typical set of operating conditions measured with the dosimetry system.
 - (ii) The difference between the measurement made in paragraph (c) (2) (i) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);
 - (iii) Source output against computer calculation;
 - (iv) Timer accuracy and linearity over the range of use;
 - (v) On-off error; and
 - (vi) Trunnion centricity.
- (d) To satisfy the requirements of paragraphs (a)(2) and (a)(3) of this section, spot-checks must assure proper operation of:
- (1) Electrical interlocks at each gamma stereotactic radiosurgery room entrance;
 - (2) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;
 - (3) Viewing and intercom systems;
 - (4) Timer termination;
 - (5) Radiation monitors used to indicate room exposures; and
 - (6) Emergency off buttons.
- (e) A licensee shall arrange for the repair of any system identified in paragraph (c) of this section that is not operating properly as soon as possible. Results of repair done should be recorded.
- (f) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.
- (g) The licensee shall retain a record of each spot-check required by paragraphs (c) and (d) and a copy of the procedures required by paragraph (b) of this section.

Section 29. Radiation Surveys.

- (a) Each licensee shall perform surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the Radioactive Source and Device Registry or equivalent.
- (b) Each licensee shall perform survey as required in paragraph (a) of this Section at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source (s).

- (c) The licensee shall retain a record of the radiation surveys made for this Section during the useful life of the machine.

Section 30. Five-Year Inspection for Teletherapy Units and Gamma Stereotactic Radiosurgery Unit.

- (a) A licensee shall have each teletherapy unit and GSR unit fully inspected and serviced during teletherapy source replacement or at intervals not to exceed **five years** whichever comes first, to assure proper functioning of the source exposure mechanism.
- (b) This inspection or servicing may only be performed by persons specifically licensed to do so by the PNRI.
- (c) The licensee shall keep a record of the inspection and servicing during the useful life of the machine. The record must contain the inspector's name, the date of inspection, the manufacturer's name and model number and serial number for both the units and source, a list of components inspected, a list of components serviced and the type of service, a list of components replaced, and the signature of the inspector.

Section 31. Possession of Survey Instruments.

A licensee shall have in its possession one or more portable radiation survey instruments capable of measuring dose rates over the range of 2 μ Sv to 10 mSv per hour.

Section 32. Possession of Reference Sources.

A licensee authorized in this Part may receive, possess, and use whenever applicable reference sources for checking the long-term stability of the ionization chamber.

Section 33. Calibration and Check of Survey Instruments.

- (a) A licensee shall calibrate or cause the calibration of its survey instruments to show compliance with this Part before first use, annually, and following any repair, unless otherwise recommended by the calibration laboratory.
- (b) A licensee shall check each survey instrument for proper operation with a dedicated check source each day prior to its use.
- (c) A licensee shall retain a record of each survey instrument calibration during the useful life of the teletherapy unit. The record must include the date of the calibration, a description of the source used and the certified exposure rates from the source, and the rates indicated by the instrument being calibrated, the calibration factors deduced from the calibration data, and the signature of the individual who performed the calibration.

Section 34. Leak Test Requirements.

- (a) A licensee in possession of any radioactive source shall follow the radiation safety and handling instructions supplied by the manufacturer, and shall maintain the instructions for the duration of source use in a legible form convenient to users.

- (b) A licensee shall test the source or cause the source to be tested for leakage before its first use unless it has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and
- (c) A licensee shall test the source for leakage at intervals not to exceed six (6) months.
- (d) A licensee shall describe and submit the procedure for taking the test samples and the instrumentation that will be used for measurement, if the licensee performs the entire-leak test procedure itself.
- (e) The licensee shall submit the name and address of the authorized or licensed Service Provider, if it avails itself of or engages the services of a Service Provider for leak testing of sealed sources.
- (f) The licensee shall retain leakage test records for the duration of use of the source. The records must contain the identity of the source, the computed activity of the source(s) at the time of the test, the Model Number, and Serial Number, the results of the analysis of the test samples in becquerels, the description of the method used, date of test, the name and signature of the individual who conducted the test.
- (g) If the leakage test reveals the presence of **185 Bq** or more of removable contamination, the licensee shall:
 - (1) Immediately withdraw the sealed source from use and secure it in accordance with the requirements in CPR Part 26; and
 - (2) File a report within **five (5) days** of the leakage test with the Institute, describing the source and equipment involved, the test results, and the action taken on the leaking source.
- (h) The licensee need not perform a leakage test on the following sources:
 - (1) Sources containing **4 MBq or less** of beta- or gamma-emitting radioactive source; and
 - (2) Sources stored and not being used. The licensee shall, however, test each source for leakage before any use or transfer unless it has been leak-tested within one (1) year before the date of use or transfer.

Section 35. Emergency Plan.

- (a) Each licensee shall establish Emergency Plan in accordance with Sec, 17.1 of CPR Part 3.
- (b) A licensee shall post at convenient visible location in the licensed facility copies of operating and emergency procedures and local rules that include the Telephone numbers of RSO and other key personnel responsible for response in the event of an emergency.

Section 36. Transfer of Radioactive Source.

- (a) Except as otherwise provided in his license, no licensee may transfer radioactive source to anyone other than:
 - (1) to PNRI; or
 - (2) to any person authorized to receive such radioactive source by a valid license issued by the Institute; or
 - (3) to any person abroad authorized to receive pursuant to an export license.

- (b) Before transferring radioactive source to a person licensed by PNRI, the licensee transferring the source, shall verify that the transferee's license is valid and authorizes receipt of the type, form and quantity of radioactive source to be transferred by having in his possession a copy of that license or a written certification by the transferee to that effect with the license number and expiration date.
- (c) Within ten (10) days after each transfer of radioactive source the licensee who made the transfer shall submit a report to PNRI showing his name, address, and license number of the type, form, and quantity of radioactive source transferred, the date transferred and the name, address and license number of the person to whom the source was transferred.

Section 37. Accidental Medical Exposure

The licensee shall promptly investigate occurrence of any of the following incidents:

- (a) deviation from the treatment prescription which includes
 - (1) wrong patient;
 - (2) wrong anatomical site;
 - (3) substantial difference from the prescribed dose; and
 - (4) wrong dose distribution or wrong dose fractionation;
- (b) any equipment failure, accident, error, mishap, or other unusual occurrence with the potential for causing a patient exposure significantly different from that intended.

Section 38. Import and Export of Radioactive Sources

The licensee shall ensure that import and export of radioactive sources are in accordance with the requirements in **Appendix A, "Requirements on the Import and Export of Radioactive Sources,"** of this Part.

Section 39. Management of Disused Radioactive Sources.

- (a) The licensee shall be responsible for the disposition of all licensed radioactive sources listed in his license.
- (b) The licensee may have the following management options to consider:
 - (1) Transfer the source to another licensee for other application consistent with the current activity level; or
 - (2) Return of the disused source to the original supplier.

Section 40. Transfer of Disused Radioactive Sources to Another Licensee.

No licensee shall transfer disused radioactive sources to another licensee unless:

- (a) He has notified and has received authorization from PNRI about such transfer;
- (b) He has submitted to the Institute appropriate information that includes:
 - (1) licensee's name, address and license number;

- (2) type, form and quantity of material to be transferred; and
 - (3) the name, address and license number of the person to whom the radioactive sources will be transferred.
- (c) Transfer is in accordance with the transport requirements provided for in CPR Part 4.

Section 41. *Return of Disused Radioactive Sources to the Original Supplier.*

A licensee shall return to the original supplier its spent sealed sources in accordance with Appendix A of this Part, on condition that the sources are packaged and shipped in a container, the design and specifications of which have been approved by PNRI.

Section 42. *Decommissioning of Teletherapy/Gamma Stereotactic Radiosurgery Units.*

- (a) Each licensee shall be responsible for the decommissioning of their teletherapy/ gamma Stereotactic Radiosurgery units or facilities.
- (b) A licensee shall submit to PNRI for approval a proposed decommissioning plan which must include:
 - (1) Description of planned decommissioning activities;
 - (2) Description of methods to assure protection of workers and the environment against radiation hazards during decommissioning;
 - (3) Description of the planned final radiation survey;
 - (4) Assurance on the availability of adequate funds for completion of decommissioning; and
 - (5) Program for the disposition of the radioactive source after decommissioning.
- (c) A licensee shall submit to PNRI, upon completion of decommissioning, a report of the results of the radiation survey performed.
- (d) A licensee shall demonstrate that the premises are suitable for unrestricted use and occupancy after decommissioning.

V. SECURITY OF SOURCES

Section 43. *Security of Teletherapy and Reference Sources.*

A licensee shall establish, document and implement security requirements of the sealed sources contained in teletherapy equipment as required in CPR Part 26, Security of Radioactive Sources to prevent unauthorized access or theft of radioactive source for possible malevolent use.

VI. EDUCATION, TRAINING AND EXPERIENCE REQUIREMENTS

Section 44. Authorized User.

A licensee shall designate an authorized user upon the endorsement and approval of the Radiation Safety Committee, who:

- (a) Is a physician duly licensed by the Professional Regulations Commission;
- (b) Is certified by an independent certifying body recognized by PNRI; and
- (c)
 - (i) Has had 200 hours of PNRI approved classroom and laboratory training in basic radionuclides techniques applicable to the use of a sealed source in a teletherapy medical unit; and
 - (ii) Has had a minimum of 4 years of residency training in a radiation therapy program under the supervision of an authorized user in a medical institution.

Section 45. Medical Physicist.

The licensee shall require the Medical Physicist to be an individual who:

- (a) Holds a Bachelor of Science degree in physics, therapeutic radiological physics, biophysics, medical physics, health physics, physical sciences or engineering; and
- (b) Has had at least 200 hours of classroom training that includes Radiation Physics, Radiation Dosimetry, Radiation Protection, Radiation Biology, and Nuclear Regulations and Licensing;
- (c) Has earned units in Physics of Radiotherapy and Practical Attachments in Radiotherapy in the MS degree program in Medical Physics or equivalent;
- (d) Has a six-month training in conventional radiotherapy procedures which shall cover treatment planning; dose calculations; localization and simulation; generation of beam data; beam calibration; and quality assurance of teletherapy equipment including treatment planning system, under the close supervision of a medical physicist, after which certification of completion of training and experience is issued by the institution.

Section 46. Radiation Safety Officer (RSO)

The licensee shall require an individual fulfilling the responsibilities of the RSO as provided in Section 17 of this Part to be an individual who:

- (a) Has a Bachelor of Science Degree in natural and physical sciences or engineering;
- (b) Has received at least 200 hours classroom and laboratory training in radiation safety covering as minimum: Radiation Physics and Instrumentation; Radiation Quantities and Measurements, Biological Effects of Ionizing Radiation, Principles of Radiation Protection International Framework, Regulatory Control, Assessment of External and Internal Exposures, Protection Against Occupational Exposure, Medical Exposure in Radiotherapy, Exposure of the Public Owing to Practices, and Intervention in Situations of Chronic and Emergency Exposure;
- (c) Has gained three-month experience under the supervision of an individual identified as RSO in a Medical Institution licensed to use radioactive sources in Teletherapy unit.

Section 47. Radiotherapy Technologist.

A licensee shall require the radiotherapy technologist to be an individual who:

- (a) Holds a Bachelor of Science Degree in **Radiologic Technology** and is duly licensed by the Philippine Professional Regulations Commission;
- (b) Has had at **least six (6) months full-time training and experience** in the operation of a teletherapy unit or GSR unit under the supervision of a medical physicist and authorized user; and
- (c) Has had 40 hours classroom training in radiation safety.

Section 48. Refresher Course.

The licensee shall require the workers to undertake a refresher course on radiation safety as appropriate and approved by PNRI every three (3) years.

VII. RECORDS, REPORTS AND NOTIFICATIONS

Section 49. Record System

- (a) The licensee shall keep/maintain and make available for inspection of PNRI records on the following:
 - (1) Radiation Safety Program;
 - (2) Security Procedures;
 - (3) Checks of permanent radiation monitor;
 - (4) Radiation Surveys from the Surface of Main Source Safe;
 - (5) Personnel exposure (current records and prior work history);
 - (6) Area surveys (dose or dose rate and contamination);
 - (7) Instrument tests and calibration;
 - (8) Tests for radioactive sealed source leakage;
 - (9) Audits and reviews of radiation safety program;
 - (10) Incident/accidents investigation reports;
 - (11) Installation, maintenance and repair work;
 - (12) Training provided;
 - (13) Evidence of health surveillance;
 - (14) Transport of radioactive source;
 - (15) Disposal of disused sources;
 - (16) Quality Control Tests;
 - (17) Results of emergency and security drills and exercises;
 - (18) Accidental Medical Exposure; and
- (b) The records required in this Part shall be retained during the useful life of the machine.

Section 50. Records of Receipt and Disposal of Disused Sealed Sources.

Each licensee shall maintain and retain records of receipt and disposal of disused radioactive sources until PNRI authorizes their disposition.

Section 51. Reporting of Incidents/Accidents.

The licensee shall make a report in writing to PNRI any incidents or accidents involving radioactive source within thirty (30) days of its occurrence.

Section 52. Reports of Teletherapy Surveys, Checks, Tests, and Measurements.

A licensee shall mail a copy of the records of the results of initial QC tests from Co-60 and GSR units, and records required in Sections 26, 27 and 28, and the reference output from the teletherapy unit source expressed as centigray per minute at 80 cm SSD, or as applicable, at the position of dose maximum from the source and determined during the full calibration. Results of the succeeding QC tests shall be kept and made available for inspection of PNRI.

Section 53. Reports of Personnel Exposure.

- (a) The licensee shall furnish a report referring to employee's total radiation exposure during the period of employment or work assignment in the licensee's facility whenever termination of employment has made. Such report shall be furnished within thirty (30) days after the exposure of the employee has been determined by the licensee or ninety (90) days after the date of termination of employment or work assignment.
- (b) At the request of an employee, each licensee shall furnish to that employee a report of that employee's total exposure to radiation as shown in records maintained by the licensee.

Section 54. Report of a Leaking Source.

A licensee shall file a report within 5 days if a leak test required by Section 38 reveals the presence of 185 Bq (0.005 μ Ci) or more of removable contamination. The written report must include the model number and serial number, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

Section 55. Report on Accidental Medical Exposure Involving Patients.

A licensee shall within 30 days after the occurrence of the incident or accident, submit to PNRI a written report which shall include:

- (a) The name of the prescribing physician;
- (b) A brief description of the incident or accident;
- (c) Cause of the incident or accident;
- (d) The calculation or estimate of the doses received and their distribution within the patient;
- (e) The effect, if any, on the individual(s) who received the administration;
- (f) The corrective measures taken or are planned to prevent recurrence;
- (g) Procedure for the implementation of the corrective measures;

- (h) Certification that the licensee notified the patient and his or her doctor about the incident or accident;

Section 56. Notification of Incidents/Accidents.

The licensee shall notify PNRI within twenty-four (hours) by telephone or by any other fast means of communications of any incidents or accidents involving radioactive source.

Section 57. Notification on Specific Changes in the License.

- (a) The licensee shall notify the **Institute** in writing within **thirty (30) days**:
 - (1) When an authorized user, medical physicist, radiation therapist permanently discontinues performance of duties under the license or has a name change, or
 - (2) When the licensee's mailing address changes.
- (b) The licensee shall mail the report to:

**The Director
Philippine Nuclear Research Institute
Commonwealth Avenue, Diliman, Quezon City**

VIII. ENFORCEMENT

Section 58. Inspections.

- (a) Each licensee shall allow authorized PNRI inspectors to enter its premises at all reasonable times and perform such inspections as may be necessary, announced or unannounced, of the radioactive sources in his/her possession and the premises, equipment and facilities where radioactive sources are used or stored.
- (b) During such inspections, the licensee shall make available to PNRI inspectors all relevant records kept pursuant to these rules and regulations at the location specified in the license.

Section 59. Violations.

- (a) A notice of violation shall be issued to any person found to have violated any rule, regulation, or order issued thereunder; or any term, condition, or limitation of any license issued thereunder.
- (b) Any license may be modified, suspended, or revoked, after due process, for any violation which the Institute determines to adversely affect the health and safety of the workers and the public.
- (c) Any person who willfully violates, attempts to violate, or conspires to violate any rule or regulation or order issued hereunder, may be guilty of a crime, and upon conviction, may be punished by a fine or imprisonment or both as provided by **Sections 64 and 65 of Republic Act No. 5207** and **Section 25 of Republic Act No. 2067**, as amended.

Section 60. Modification and Revocation of License.

- (a) The terms and conditions of each license issued pursuant to the regulations in this Part shall be subject to amendment, revision or modification by reason of amendments to these regulations and the Act, or by reason of rules, regulations and orders issued by PNRI in accordance with the terms of the Act.
- (b) Any license may be revoked, suspended or modified, in whole or in part, for any material false statement in the application, or for violation of, or failure by the licensee to observe, any of the terms and conditions of the license or any of the provisions of the Act, or any of the rule, regulation or order of the PNRI.
- (c) Except in cases of willful violation or where immediate action is required in order to protect public health and safety or the security of the source, no order for the suspension, modification or revocation of the license shall become effective until the licensee shall have afforded the opportunity to be heard.
- (d) A license maybe modified by PNRI, or upon the request of the licensee, when:
 - (1) The licensee decides to discontinue any specific licensed activity authorized in the license or request for another authorization to undertake another licensed activity prescribed in this Part;
 - (2) PNRI determines that the licensee can no longer perform the specific licensed activity authorized in the license; or
 - (3) The licensee has ceased to perform a licensed activity during a two (2) year period.
- (e) Any person who willfully violates, attempts to violate or conspires to violate any rule or regulation or order issued hereunder, may be guilty of a crime, and upon conviction, may be punished by a fine or imprisonment or both as provided by Sec. 64 and 65 of republic Act No. 5207, as amended.

IX. EFFECTIVITY

Section 61. Effective Date.

The regulations in this Part shall take effect **fifteen (15) days** following the publication in the **Official Gazette** or in a **newspaper of general circulation**.

Approved:

(Sgd.)ALUMANDA M. DELA ROSA, Ph. D.
Director, PNRI

Date: JULY 28, 2008

APPENDIX A

REQUIREMENTS ON THE IMPORT AND EXPORT OF RADIOACTIVE SOURCES

These requirements on the import and export of **Categories 1 and 2** radioactive sources are in conformance with the import and export provisions in Parts 4 and 26 of the Code of PNRI Regulations (CPR), the IAEA Code of Conduct on the Safety and Security of Radioactive Sources and the IAEA Guidance Document on the Import and Export of Radioactive Sources. These requirements do not apply to radioactive sources within military or defense programs.

I. Import of Radioactive Sources.

- (a) Licensees intending to import radioactive sources in Categories 1 and 2 of **Table 1** shall apply to PNRI for an authorization and must receive such authorization prior to import.
- (b) The application shall include the following information:
 - (1) name of the exporter and photocopy of exporter's valid license issued by the competent authority of the exporting country;
 - (2) exporter location and legal address or principal place of business;
 - (3) radionuclide data, activity, and uses of the radioactive source(s);
 - (4) name of licensed local distributor and photocopy of distributor's valid license issued by PNRI; and
 - (5) the provisions for return or disposal of the radioactive source once it becomes disused, including copies of any contracts with distributor and exporter to re-export for return and proper management of the source.
- (c) Licensees shall ensure that the exporter of the radioactive sources is authorized by the Competent Authority of the exporting country to export such sources to the Philippines in accordance with laws and regulations of that country.
- (d) Licensees shall provide the Competent Authority of the exporting country with the following information in writing:
 - (1) name of the recipient;
 - (2) recipient location and legal address or principal place of business;
 - (3) radionuclide data, activity and reference date;
 - (4) intended purpose and proposed use(s) of the radioactive source; and
 - (5) a suggested timeframe for a decision on the request to import.
- (e) A licensee who is only authorized by PNRI to import, sell or distribute radioactive sources shall import these sources only if the recipient or consignee in the Philippines has a valid PNRI license to receive the source and is capable to manage the source consistent with **Section 11 of CPR Part 26**.
- (f) Licensees shall ensure that the Exporting Country allows the re-entry of spent or disused sources if, in the framework of that Country's national laws, it has approved that spent or disused sources be returned to a manufacturer authorized to manage the spent or disused sources.
- (g) Licensees shall secure from the PNRI:

- (1) A **request for release** which is submitted to the Bureau of Customs Officer to allow the release of the radioactive source shipment from the customs cargo hold area; and
 - (2) An **Authority to Transport** Certificate wherein PNRI gives approval to transport the radioactive source shipment to the recipient location.
- (h) Licensees shall ensure that the import of radioactive sources is in accordance with CPR Part 4, "Regulations for the Safe Transport of Radioactive Materials in the Philippines".

II. Export of Radioactive Sources.

- (a) Licensees intending to export radioactive sources in Categories 1 and 2, particularly **disused or spent sources**, shall apply to PNRI for an authorization and must receive such authorization prior to exportation.
- (b) The application for export shall include:
 - (1) copies of agreements or contracts to re-import the source once it becomes disused;
 - (2) confirmation letter from the Competent Authority of the importing country that the recipient is authorized to receive and possess the radioactive source or sources to be exported in accordance with its laws and regulations; and
 - (3) a copy of the recipient's valid authorization issued by the Competent Authority of the importing country.
- (c) Licensees involved in the export of radioactive sources in Categories 1 and 2 of Table 1 shall ensure that the importing country has the appropriate technical and administrative capability, resources and regulatory infrastructure needed for the management of the radioactive sources.
- (d) Licensees shall take into consideration the risk of diversion or malicious acts involving radioactive sources by verification of the following information:
 - (1) whether the recipient has been engaged in illegal procurement of radioactive materials;
 - (2) whether an import or export authorization for radioactive sources has been denied to the recipient or importing country; or
 - (3) whether the recipient or importing country has diverted, for purposes inconsistent with the Code of PNRI Regulations, any import or export of radioactive sources previously authorized.
- (e) Licensees intending to export Category 1 and 2 sources shall notify the Competent Authority of the importing country, and should receive confirmation of such notification at least 7 days in advance of each shipment.
- (f) Licensees shall notify the Competent Authority of the importing country with the following information in advance, as applicable:
 - (1) estimated date of export,
 - (2) name and address of the exporting facility,
 - (3) name and address of the recipient,
 - (4) radionuclide, activity, and reference date,
 - (5) aggregate activity level, and
 - (6) number of radioactive sources and their unique identifiers (e.g., physical and chemical form).

- (g) Licensees shall provide PNRI with a copy of the above notification and secure from PNRI a written authorization to transport the radioactive source(s).
- (h) Licensees shall show proof to PNRI that the exported radioactive sources have been received by the authorized recipient.

III. Transfer of Radioactive Sources.

Licensees involved in the import and export of radioactive sources shall ensure that transfers are undertaken with a valid written authorization from PNRI.

IV. Transport of Radioactive Sources.

- (a) Licensees involved in the import or export of radioactive sources shall ensure that the transport of radioactive sources, either domestically or internationally, is in compliance with the requirements of CPR Part 4, "Regulations for the Safe Transport of Radioactive Materials in the Philippines", and all applicable national and international governmental regulations.
- (b) Licensees shall ensure that the import or export of radioactive sources is conducted in a manner consistent with existing relevant international standards relating to the transport of radioactive materials.
- (c) Licensees shall ensure that the transport of radioactive sources through the territory of a transit or transshipment country is conducted in a manner consistent with existing relevant international standards relating to the transport of radioactive materials, in particular paying careful attention to maintaining continuity of control during international transport.
- (d) If the conditions in **II(c)** with respect to a particular export cannot be satisfied, that export may be authorized by PNRI in exceptional circumstances if an alternative arrangement has been made to ensure the source will be managed in a safe and secure manner.

TABLE I. ACTIVITIES CORRESPONDING TO THRESHOLDS OF CATEGORIES**

Radionuclide	Category 1*	
	1000 x D	
	(TBq)	(Ci)
Am-241	6.E+01	2.E+03
Am-241/Be	6.E+01	2.E+03
Cf-252	2.E+01	5.E+02
Cm-244	5.E+01	1.E+03
Co-60	3.E+01	8.E+02
Cs-137	1.E+02	3.E+03
Gd-153	1.E+03	3.E+04
Ir-192	8.E+01	2.E+03
Pm-147	4.E+04	1.E+06
Pu-238	6.E+01	2.E+03
Pu-239b/Be	6.E+01	2.E+03
Ra-226	4.E+01	1.E+03
Se-75	2.E+02	5.E+03
Sr-90 (Y-90)	1.E+03	3.E+04
Tm-170	2.E+04	5.E+05
Yb-169	3.E+02	8.E+03

* **“Category 1 sources”**, if not safely managed or securely protected, would be likely to cause permanent injury to a person who handled them, or were otherwise in contact with them, for more than a few minutes. It would probably be fatal to be close to this amount of unshielded radioactive material for a period of a few minutes to an hour. These sources are typically used in practices such as **Co-60 irradiators** and **teletherapy**.

** Categorization is provided by activity levels for radionuclides that are commonly used. These are based on D-values which define a dangerous source i.e., a source that could, if not under control, give rise to exposure sufficient to cause severe deterministic effects. A more complete listing of radionuclides and associated activity levels corresponding to each category, and a fuller explanation of the derivation of the D-values, may be found in **Appendix I of CPR Part 26**.